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February 27, 2009

Dr. John C. Lechleiter, Ph.D.
Chairman, President, and Chief Executive Officer
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Lechleiter:

The Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are investigating the removal of Dr. Sanjay Kaul, M.D., M.P.H, from the Food and Drug Administration's advisory committee meeting on an anti-clotting drug, prasugrel.

Dr. Kaul, a cardiologist at Cedars-Sinai Heart Institute, is a voting member of FDA's Cardiovascular and Renal Drugs Advisory Committee. Before joining the advisory committee, Dr. Kaul had authored research abstracts questioning prasugrel's safety and effectiveness. According to FDA, Dr. Kaul submitted these abstracts and all other required information during FDA's conflict screening process before FDA selected him for the panel.¹

According to press reports, the advisory committee met on February 3, 2009, to consider the new drug application for prasugrel. These accounts stated that Eli Lilly, the manufacturer of prasugrel, contacted FDA officials before the meeting to raise concerns about Dr. Kaul's participation in the advisory committee.² FDA officials then reportedly disinvited Dr. Kaul from the meeting due to an alleged "intellectual bias" against the drug.³

As part of our investigation, we request that Eli Lilly produce the following documents:

¹ "Mistakes" Made: FDA Acknowledges Lilly Phoned to Question Sanjay Kaul's Inclusion on Prasugrel Panel (Feb. 20, 2009) (online at www.theheart.org/article/943511.do).

² FDA: "Mistake" Not To Include Doctor At Eli Lilly Drug Panel, Dow Jones Newswire (Feb. 23, 2009).

³ FDA Admits Error in Barring Doctor From Panel, Associated Press (Feb. 24, 2009).


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1. All documents and communications, including email, to or from officials at FDA, Eli Lilly, or any other person or entity relating to Dr. Kaul; and
2. A log of communications, including phone calls, to or from officials at FDA, Eli Lilly, or any other person or entity relating to Dr. Kaul's research on prasugrel or his participation in the February 3, 2009, advisory committee meeting, including the date of the communication, the names of the participants, and a description of the matters discussed.

Please produce these documents by Friday, March 13, 2009. An attachment to this letter provides additional information on how to respond to the Committee's request. If you have any questions regarding this request, please contact Michael Gordon or Stacia Cardille with Committee staff at (202) 226-2424.

Sincerely,


Henry A. Waxman
Chairman


Bart Stupak
Chairman
Subcommittee on Oversight and
Investigations

Enclosure

cc: Joe Barton
Ranking Member
Committee on Energy and Commerce

Greg Walden
Ranking Member
Subcommittee on Oversight and
Investigations